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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,669	03/23/2007	Steven Coutre	4-33233A	2341

1095 7590 06/07/2010

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 101/2
EAST HANOVER, NJ 07936-1080

EXAMINER	
JEAN-LOUIS, SAMIRA JM	

ART UNIT	PAPER NUMBER
1627	

MAIL DATE	DELIVERY MODE
06/07/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/560,669	COUTRE, STEVEN	
	Examiner	Art Unit	
	SAMIRA JEAN-LOUIS	1627	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 April 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *16 April 2010*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *20-39*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1627

The Examiner acknowledges receipt of the amended claims filed on 04/16/10. However, such amendment will not be entered as they are not deemed to place the application in better form for appeal.

Applicant's argument with respect to the 103(a) rejection has been fully considered. Applicant argues that such rejection is not proper as the Examiner has not established that there had been a finite number of identified, predictable potential solutions to the problem solved by the present invention. In fact, applicant argues that the prior art merely discloses a theoretical basis to experiment with kit inhibitors for the treatment of mastocytosis. Such arguments are however not found persuasive as the Examiner maintains that the prior art does indeed render obvious applicant's invention. As previously stated in the Final Rejection dated 12/17/09, Longley does indeed teach that mutations including the D816V mutation is involved in the genesis of mastocytosis. Additionally, Longley teaches that studies of various c-kit inhibitors demonstrated that such inhibitors were effective in inhibitng both wild type and mutated c-kit and further suggested the use of kit inhibitors for the treatment of mastocytosis. Consequently, the Examiner contends that a finite number of solutions was indeed given by the prior art and that is the use of kit inhibitors for the treatment of mastocytosis including the form dealing with the D816V mutation. Longley did not teach the use midostaurin for treating mastocytosis. Goekjian however teaches that midostaurin is known to achieve a greater level of kinase selectivity of c-kit and potential therapeutic index along with non-toxic side effects. As a result, the Examiner contends that one of ordinary skill in the art would have indeed found it obvious to try midostaurin (a c-kit inhibitor as taught by Goekjian) for the treatment of mastocytosis since Goekjian teaches that such inhibitor is highly selective and possesses no toxic side effects. While applicant argues that many of the kit inhibitors tested yielded results that could be seen as non-effective against mastocytosis that is resistant to imatinib, such arguments are not persuasive as Longley clearly demonstrated that the kit-inhibitors were effective at various levels. Again, the examiner reminds applicant that treatment does not equate to 100% cure and given that all inhibitors exerted some inhibitory effects, one of ordinary skill in the art wouild have indeed found it obvious to try midostaurin and would have had a reasonable expectation of success.

Applicant's arguments that the disclosures of Longley and Ma would not lead a skilled artisan to reasonably expect for kit inhibitors to be useful for treating mastocytosis that is imatinib resistant and which possesses a KIT mutation have been fully considered. Such arguments are however not found persuasive as the Examiner contends that Ma teaches that adult mastocytosis which is characterized by mutations in the c-kit codon 816, the same mutation tested by Longley, were resistant to imatinib but possessed the same D816V mutation. Consequently, the Examiner contends that it would have been obvious for one skilled in the art to try midostaurin in the treatment of mastocytosis resistant to imatinib since Ma teaches that such imatinib resistant mastocytosis form also possessed a D816V mutation and in view of Longley who demonstrated that c-kit inhibitors were effective in inhibiting c-kit in cells with D816V mutation and in further view of Goejian who teaches that midostaurin is highly selective against the c-kit kinase. Though applicant stipulated that a long felt need was met by the invention the Examiner respectfully points out that a long-felt need also requires objective evidence that an art recognized problem existed in the art for a long period of time without solution. In such a case, the Examiner maintains that a solution was indeed provided by Longley and Goekjian in view of Ma and thus one of ordinary skill in the art based on such disclosure would have had a reasonable expectation of success in treating mastocytosis and imatinib-resistant mastocytosis given the disclosure of Longley.

Thus, for the foregoing reasons, the Examiner maintains that the rejections of record were indeed proper and are therefore maintained.